REMARKS/ARGUMENTS

Claims 1 - 11 and 23-48 remain in this application.

Claims 12-22 have been canceled.

Claims 1-11 and 29-40 have been withdrawn.

Claims 41-48 have been added.

In the specification, the paragraphs beginning at pages 1,32,33 and 35 have been amended to correct minor editorial problems. Claim 1-11 and 29-40 have been withdrawn as the result of an earlier restriction requirement.

As a result of the instantly filed amendments, Examiner Blanchard, during a teleconference on Aug. 7, 2006, tentatively agreed that the previous restriction would be withdrawn and claims 1-11 and 23-48 considered herein, with the understanding that the claims drawn to those inventions would not be pursued in co-pending S.N. 10/810,165.

In response to the Office Action of May 5, 2006, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Applicants appreciate the Examiner's acknowledgement of entry of the preliminary amendment of 14 March 2005.

Election/Restrictions:

Applicant's election without traverse of the invention of Group II, claims 23-28 in the reply filed on 13 February 2006 is acknowledged.

Claims 1-11 and 29-40, which are currently withdrawn from further consideration, are nevertheless instantly amended *supra*. Applicants submit that the instant amendments modify all of the pending claims so that they now similarly rely upon the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as PTA-4621 for patentability, and as such, withdrawal of the restriction requirement and examination of said claim is hereby requested.

Claims 23-28 are under examination.

Specification

The disclosure stands objected to because of the following informalities:

a. At pg. 1, lines 6-7 need to be updated with the U.S. Patent number for USSN 09/727,361, field November 29, 2000, which is U.S. Patent 6,657,048.

Accordingly, the required insertion has been made, and the remaining disclosure has been reviewed, as per the Examiner's request.

b. The use of the trademark SYPRO RubyT' has been noted in this application (see specification pg. 32, line 20, pg. 33, line 20, pg. 36, line 3). It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicant has reviewed the trademark status of the ruby protein gel stain from SYPRO and determined that only the brand name SYPRO appears to be trademarked. Accordingly, the disclosure has been amended throughout to now refer to "SYPRO Ruby protein gel stain".

It is Applicants belief that this is an accurate representation of the product referred to, and recognizes the SYPRO trademark.

Claim Objections:

Claim 23 stands objected to as being grammatically incorrect in the recitation "which expresses CD44 antigenic moiety...".

Accordingly, the claim has been amended to recite "which expresses a CD44 antigenic moiety" to overcome this objection.

Claim Rejections - 35 USC § 112:

Claims 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 23-28 are deemed indefinite in the recitation of "having the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4621" in claim 23 because the exact meaning of the phrase is not known.

Further, given the circular language of claim 23, the Examiner questions whether the monoclonal antibody, which binds the CD44 antigenic moiety is the antibody that has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4621, and therefore alleges that one or ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

b. Claim 23-28 are further deemed to be indefinite in the recitation "monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4621" in claim 23, and the Examiner suggests that this deficiency can be overcome by amending claim 23 to recite "the monoclonal antibody produced by the hybridoma deposited with the ATCC as PTA-4621".

Accordingly, claim 23 has now been amended to recite:

Claim 23. A process for mediating cytotoxicity of a human tumor cell which expresses a CD44 antigenic moiety on the cell surface, characterized as being bound by the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as PTA-4621 or antigen binding fragments thereof comprising:

contacting said human tumor cell with said isolated monoclonal antibody or antigen binding fragment thereof, which enables binding of said isolated monoclonal antibody or antigen binding fragments thereof with said expressed CD44 antigenic moiety;

whereby cell cytotoxicity occurs as a result of said binding.

This amendment, and similar amendments made to the previously withdrawn independent claims, are believed to obviate the instant rejection under 35 USC 112.

Claim Rejections - 35 USC § 112:

Claims 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims are alleged to contain subject matter, which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The preliminary amendment filed 3/14/2005 has been deemed to have introduced new matter into the claims.

The Examiner explains that as originally filed on 8/22/2003, claims 23-28 were drawn to a process for mediating cytotoxicity of a human tumor cell expressing a CD44 antigenic moiety on the cell surface comprising contacting said tumor cell with an isolated monoclonal antibody or antigen binding fragments thereof encoded by the clone deposited with the ATCC as Accession Number PTA-4621, whereby cytotoxicity occurs as a result of said binding and wherein the isolated monoclonal antibody or antigen binding fragments thereof are humanized, chimerized, murine or conjugated to a therapeutic moiety and the human tumor is selected from colon, ovarian, lung and breast.

The Examiner further points out that preliminary amendment filed 3/14/2005 amended the claimed process to recite wherein the human tumor cell expressing a CD44 antigenic moiety on the cell surface is contacted with an isolated monoclonal antibody or antigen binding fragments thereof which bind to said expressed CD44 antigenic moiety, said antigenic moiety characterized as

being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by the clone deposited with the ATCC as Accession Number PTA-4621.

The Examiner indicates that there is insufficient written support for the presently claimed subgenus of monoclonal antibodies that have the "identifying characteristics" of the monoclonal antibody produced by clone because the "identifying characteristics" have not been clearly set forth in the as filed specification. Further, the specification at pp. 22-23, particularly pg. 23, lines 13-15, discloses that monoclonal antibody H460-16-2 (produced by clone PTA-4621) has superior anti-tumor properties in comparison with previously described anti-CD44 antibodies. Thus, the specification as filed does not clearly disclose or provide adequate guidance and direction to the presently claimed subgenus of anti-CD44 monoclonal antibodies that have the "identifying characteristics" of the monoclonal antibody produced by the clone deposited with the ATCC as PTA-4621.

Accordingly, these limitations have been removed from the claims.

Priority:

With regard to the question of priority, the Examiner points out that the later-filed application (i.e., the instant application) must be an application for a patent for an invention, which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior filed application, Application Nos. 10/603,2003; 09/727,361; and 09/415,278, fail to provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The Examiner indicates that prior application numbers 10/603,000, 09/727,361, and 09/415,278 do not provide adequate written support for the presently claimed subgenus of anti-CD44 antibodies having the relevant identifying characteristics of the monoclonal antibody produced by the clone deposited with the ATCC as PTA-4621 as discussed supra (see item no. 11 above), and accordingly, the effective filing date of claims 23-28 for

purposes of applying prior art is deemed to be the filing date of the instant application, i.e., 8/22/2003.

The instant amendments, as discussed *supra* are submitted to obviate this question and perfect Applicants' priority rights.

Claim Rejections - 35 USC § 102:

Claims 23-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Tarin et al [a] (US Patent 5,879,898, 5/17/1995, IDS reference filed 8/22/2003).

Claims 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarin et al [b] (WO 94/12631, published 6/9/1994).

Claims 23-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al [a] (US 2004/0001789 A1, priority to 11/29/2000, IDS reference filed 9/28/2005) or Young et al [b] (2004/0105815 A1, priority to 11/29/2000, IDS reference field 9/28/2005)or Young et al [c] (U.S. Patent 6,657,048, filed 11/29/2000, IDS reference filed 9/28/2005).

Claims 23-28 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 11/364,013 which has a common inventor with the instant application.

Copending Application No. 11/364,013 teaches a method of mediating cytotoxicity of human breast, colon, ovarian and lung tumor cells comprising administering monoclonal antibody H460-16-2, produced by hybridoma PTA-4621, or an antigen-binding fragment thereof (i.e., Fv, (Fv)2, Fab, Fab', F(ab)2), wherein the monoclonal antibody is chimeric, humanized, or murine as well as conjugated to a toxin, chemotherapeutic, or radioactive label (see entire document, particularly Examples 8 and 10 and pp. 50-63 and claims). Thus, monoclonal antibody H460-16-2 produced by hybridoma PTA-4621 and modified forms thereof (i.e., antigen-binding fragments, chimeric, humanized and conjugates) are species that read upon the presently claimed subgenus of antibodies and necessarily have all of the relevant identifying characteristics of the monoclonal antibody produced by the clone deposited with the ATCC as PTA-4621 because the antibodies are identical.

Double Patenting:

Claims 23, 25 and 27 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 23, 25 and 27 of copending Application No. 10/810,165.

Instant claims 23, 25 and 27 are drawn to a process for mediating cytotoxicity of a human tumor cell which expresses a CD44 antigenic moiety on the cell surface comprising contacting said human tumor cell with an isolated monoclonal antibody or antigen binding fragment thereof, said antibody or antigen binding fragment thereof being an isolated monoclonal antibody or antigen binding fragment thereof which binds to said expressed CD44 antigenic moiety, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4621, whereby cell cytotoxicity occurs as a result of said binding and wherein the monoclonal antibody or antigen-binding fragment thereof is murine or is conjugated with a member selected from the group consisting of cytotoxic moieties, enzymes, radioactive compounds and hematogenous cells.

Claims 23, 25 and 27 of copending Application No. 10/810,165 are also drawn to a method of process for mediating cytotoxicity of a human tumor cell which expresses a CD44 antigenic moiety on the cell surface comprising contacting said human tumor cell with an isolated monoclonal antibody or antigen binding fragment thereof, said antibody or antigen binding fragment thereof being an isolated monoclonal antibody or antigen binding fragment

thereof which binds to said expressed CD44 antigenic moiety, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4621, whereby cell cytotoxicity occurs as a result of said binding and wherein the monoclonal antibody or antigen-binding fragment thereof is murine or is conjugated with a member selected from the group consisting of cytotoxic moieties, enzymes, radioactive compounds and hematogenous cells.

Thus, claims 23, 25 and 27 of copending Application No. 10/810,165 are of identical scope of instant claims 23, 25 and 27.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 24, 26 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 26 and 28 of copending Application No. 10/810,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 24, 26 and 28 are drawn to a process for mediating cytotoxicity of a human tumor cell which expresses a CD44 antigenic moiety on the cell surface comprising contacting

said human tumor cell with an isolated monoclonal antibody or antigen binding fragment thereof, said antibody or antigen binding fragment thereof being an isolated monoclonal antibody or antigen binding fragment thereof which binds to said expressed CD44 antigenic moiety, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4621, whereby cell cytotoxicity occurs as a result of said binding, wherein the monoclonal antibody or antigen-binding fragment thereof is humanized or chimerized and wherein the human tumor cell is obtained from a tumor originating in a tissue selected from the group consisting of colon, ovarian, lung and breast tissue and claims 24, 26 and 28 of copending Application No. 10/810,165 are also drawn to said process for mediating cytotoxicity of a human tumor cell, wherein the monoclonal antibody or antigen-binding fragment thereof is humanized or chimerized and wherein the human tumor cell is obtained from a tumor originating in a tissue selected from the group consisting of colon, ovarian, lung, prostate and breast tissue. Thus, instant claims 24, 26 and 28 would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because it would have been obvious to apply the method of

claims 24, 26 and 28 of copending Application No. 10/810,165 for mediating cytotoxicity of human colon, ovarian, lung or breast tumor cells.

Claims 23-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/403,516. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-6 of copending Application No. 10/403,516 are drawn to a method of mediating cytotoxicity of a human tumor cell which expresses gp96 on the cell surface comprising contacting said tumor cell with an isolated monoclonal antibody or antigen-binding fragment thereof encoded by the clone deposited with the ATCC as accession number PTA-4621 (interpreted as the monoclonal antibody produced by the hybridoma deposited as PTA-4621 and antigen-binding fragments produced therefrom), whereby cell cytotoxicity occurs as a result of said binding and the monoclonal antibody or antigen-binding fragment thereof is humanized, chimeric or murine or is conjugated to a cytotoxic moiety, enzyme, radioactive compound or hematogenous cell and the tumor is a colon, ovarian, prostate or beast tumor. Thus, method of mediating cytotoxicity using the monoclonal antibody produced

by hybridoma PTA-4621 and modified forms produced therefrom (i.e., antigen-binding fragment, humanized and chimeric antibodies) are species that read upon the subgenus of anti-CD44 antibodies having relevant identifying characteristics of the monoclonal antibody produced by the clone deposited with the ATCC as PTA-4621. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 23-28 are directed to an invention not patentably distinct from claims 1-6 of commonly assigned Application No. 10/403,516. Specifically, see above.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 23-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/603,000 in view of Tarin et al [b] (WO 94/12631, published 6/9/1994).

Claims 23-28 are directed to an invention not patentably distinct from claims 1-8 of commonly assigned Application No. 10/603,000. Specifically, see above.

Claims 23-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 10-16, 20-21 and 24-28 of copending Application No. 11/364,013. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 5, 10-16, 20-21 and 24-28 of copending Application No. 11/364,013 are drawn to a method initiating antibody induced cellular cytotoxicity of cancerous cells in a human tumor tissue sample comprising contacting said human tumor tissue sample with the isolated monoclonal antibody encoded by a clone deposited with the IDAC as accession number 280104-06 (i.e., the monoclonal antibody produced by IDAC accession number 280104-06) or a cellular cytotoxicity inducing ligand thereof, which ligand is characterized by an ability to competitively inhibit binding of

said isolated monoclonal antibody to its target antigen; and a method of treating a human tumor susceptible to antibody induced cellular cytotoxicity in a mammal comprising administering the isolated monoclonal antibody encoded by a clone deposited with the IDAC as accession number 280104-06 or a cellular cytotoxicity inducing ligand thereof, which ligand is characterized by an ability to competitively inhibit binding of said isolated monoclonal antibody to its target antigen, wherein the monoclonal antibody or ligand is conjugated to a cytotoxic moiety, a radioisotope, is humanized or chimerized or activates complement (i.e., CDC) or mediates antibody dependent cellular cytotoxicity (ADCC); and a process for treating a human cancerous tumor which expresses human CD44 antigen comprising administering at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes as those recognized by a hybridoma selected from hybridoma cell line H460-16-2 having ATCC accession number PTA-4621 and hybridoma cell line AR37A335.8 having IDAC accession number 280104-06, optionally in conjunction with at least one chemotherapeutic agent (i.e., interpreted as a cytotoxic moiety conjugated to the monoclonal antibody or ligand); and a method for initiating antibody induced cellular cytotoxicity of cancerous cells in a tissue sample selected from a human tumor

comprising providing an anti-CD44 chimeric antibody or ligand thereof that is characterized by an ability to competitively inhibit binding of CD44 with the isolated monoclonal antibody encoded by the clone deposited with the ATCC as accession number PTA-4621 and a method or process of treating a human tumor which expresses CD44 comprising administering an anti-CD44 chimeric antibody or ligand thereof that is characterized by an ability to competitively inhibit binding of CD44 with the isolated monoclonal antibody encoded by the clone deposited with the ATCC as accession number PTA-4621. Thus, claims 5, 10-16, 20-21 and 24-28 of copending Application No. 11/364,013 are drawn to CD44 monoclonal antibody species that are characterized as binding the same epitope or epitopes (i.e., competitively inhibits) as those recognized by a monoclonal antibody produced by the clone deposited with IDAC as accession number 280104-06 and the clone deposited with the ATCC as accession number PTA-4621, which is merely one "identifying characteristic" of a the monoclonal antibodies produced by clones 280104-06 and PTA-4621 and instant claims 23-28 are inclusive to a method or process for mediating cytotoxicity both in vitro and in vivo.

Applicant now believes all grounds of rejection to be obviated by a combination of narrowing of claim scope and perfection of Applicants' rights of priority.

It is submitted that the instant amendments obviate the rejections over Tarin, either singly or in any combination.

It is further submitted that the instant amendments serve to perfect Applicants' rights for priority to S.N. 10/603,000, 09/727,361 09/415,278, and 11/364,013, thereby obviating the rejections under 35 USC 102(e) over US 2004/0001789, 2004/0105815, and U.S. patent 6,657,048 as prior art references.

Furthermore, all were commonly owned, as evidenced by the attached assignment documents, as recorded in the U.S.P.T.O.

With respect to the double patenting rejection over S.N. 10/810,165, it is agreed that those claims will not be pursued and the subject matter thereof will, instead, be included in the instant application.

With respect to the rejection over 10/403,516, that rejection has been obviated by abandonment of the application by failure to respond to the Office action dated 01/13/2006.

It is Applicants' belief that all outstanding grounds of rejection are now obviated in view of the arguments and

amendments submitted herewith, along with the showing of common ownership.

Should any ground inadvertently not have been obviated, the Examiner is requested to contact Applicants' representative via telephone, in order that the appropriate corrections can be made.

SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,

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Total Assignments: 1

Patent #: NONE **Issue Dt:** **Application #:** 10603000 **Filing Dt:** 06/23/2003

Publication #: US20040105815 **Pub Dt:** 06/03/2004

Inventors: David S. F. Young, Helen P. Findlay, Susan E. Hahn, Miyoko Takahashi

Title: Cancerous disease modifying antibodies

Assignment: 1

Reel/Frame: 014789/0286 **Recorded:** 12/11/2003 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: YOUNG, DAVID S.F. **Exec Dt:** 12/03/2003

FINDLAY, HELEN P. **Exec Dt:** 12/03/2003

HAHN, SUSAN E. **Exec Dt:** 12/03/2003

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Patent #: 6657048 **Issue Dt:** 12/02/2003 **Application #:** 09727361 **Filing Dt:** 11/29/2000

Publication #: US20020041877 **Pub Dt:** 04/11/2002

Inventors: David S. F. Young, Miyoko Takahashi

Title: INDIVIDUALIZED ANTI-CANCER ANTIBODIES

Assignment: 1

Reel/Frame: 012574/0652 **Recorded:** 01/23/2002 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: YOUNG, DAVID S.F. **Exec Dt:** 12/17/2001

TAKAHASHI, MIYOKO **Exec Dt:** 12/17/2001

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Patent #: 6180357 **Issue Dt:** 01/30/2001 **Application #:** 09415278 **Filing Dt:** 10/08/1999

Inventors: DAVID S.F. YOUNG, MIYOKO TAKAHASHI

Title: INDIVIDUALIZED ANTI-CANCER ANTIBODIES

Assignment: 1

Reel/Frame: 010413/0249 **Recorded:** 12/02/1999 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: YOUNG, DAVID S.F. **Exec Dt:** 10/01/1999

TAKAHASHI, MIYOKO **Exec Dt:** 10/01/1999

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11/364,013 Cytotoxicity mediation of cells evidencing surface expr

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Total Assignments: 1

Application #: 11364013 **Filing Dt:** 02/28/2006 **Patent #:** NONE

PCT #: NONE **Publication #:** NONE

Inventors: David S. F. Young, Helen P. Findlay, Susan E. Hahn, Lisa M. Cechetto, Fortunata McConke

Title: Cytotoxicity mediation of cells evidencing surface expression of CD44

Assignment: 1

Reel/Frame: 017944 / 0706 **Received:** 06/06/2006 **Recorded:** 06/02/2006

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

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